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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/441,875	11/17/1999	DAVID E. CHARLTON	CWP-012CN3	5134

21323 7590 12/28/2001

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EXAMINER

DO, PENSEE T

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/28/2001

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/441,875

Applicant(s)

CHARLTON ET AL.

Examiner

Pensee T. Do

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: _____

DETAILED ACTION

Request for Continue Examination

1. The Request for Continue Examination filed on October 1, 2001 based on parent Application No. 09/441,875 is acceptable and a RCE has been established. An action on the RCE follows.

Amendment Entry

2. The after-final amendment filed on September 20, 2001 has been entered.

Withdrawn Rejections

3. The obvious-type double patenting rejection is withdrawn herein since applicant filed a Terminal Disclaimer.

Claim Rejections - 35 U.S.C. § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- Claims 27-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown, III et al. (EP 217 403 A2).
- Brown has a test device (10) comprising a casing (14) defining a sample inlet and viewing window (fluid chamber 7) and having disposed therein a test strip comprising a porous fiber matrix 12 (equates the sorbent material which defines a flow path for transporting the liquid sample therealong from a sample contact region to a test site and a control site) and a test site (34) comprising an immobilized first protein to a

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ligand, and a control site (32) comprising immobilized second protein (i.e. an immobilized binder which binds to the conjugate, which conjugate binds to the ligand), and a filter means (22), which device is useful for competitive, sandwich and indirect assays. Chorionic gonadotropin is an explicitly illustrated ligand (example 3). Particles coated with first protein are immobilized within the porous fiber matrix 12 (see col. 4, line 49-col. 5, line 2). The first protein and second protein consists of a variety of monoclonal antibodies or polyclonal antibodies. (See col. 5, lines 54-56). The sorbent means 20 disposed in the casing 14 is for absorbing excess fluid during the use of the assay device. The absorbent means 20 comprises one or more layers of material and is in physical contact with the barrier material 18, when used, or with the reaction matrix 12. (See col. 10, lines 29-46).

Response to Arguments

- Applicant's arguments filed September 20, 2001 have been fully considered but they are not persuasive.
- Regarding the 102(b) rejection by Brown, III et al. for claims 14-26, applicant submits that the invention is directed to a test device which comprises a test strip (defined as a long, narrow piece of material) and the test strip comprises a sorbent material that permits lateral flow from a sample contact region to a test site and a control site. Applicant argues that Brown fails to teach a test strip as a long, narrow piece of material which permits lateral flow from the sample contact region to a test site and a control site. Applicant also argues that Brown fails to disclose colored particulate material.

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- A test strip, regardless of size and shape, has one unique function, that is to transport materials such as fluid sample. Since Brown's disk-shaped test strip performs the same function, it inherently reads on the test strip of the invention. Furthermore, applicant fails to describe the specific shape of the claimed test strip in the specification. One skilled in the art would be able to vary the size and shape of the test strip according to his/her preference without alternating the functions of the test strip. The sorbent material of Brown does not equate the sorbent material of the invention. Rather, the porous fiber reaction matrix is the claimed sorbent material. Responding to the argument that Brown lacks the teaching of lateral flow, Brown teaches that particles coated with first protein and immobilized second protein are on the reaction matrix. Inherently, the test site and the control site must be in lateral flow communication. Regarding the argument about the colored particles, since Brown teaches a viewing window and particulate labels (particles coated with first protein), the reference inherently reads on colored particles as being used as labels for the assay.
- Applicant also argues that the device of Brown III does not allow automatic assays to be carried out. Instead, Brown III envisions other formats, all require multiple sequential manipulative steps.
- In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., automatic assay performance) are not recited in the rejected claim(s). Although the claims are interpreted in light of the

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specification, limitations from the specification are not read into the claims.

See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims of the invention does not exclude manipulative steps. Furthermore, the claims are drawn to a device, not a method.

- Applicant also submits that Brown III fails to teach a conjugate comprising a colored particulate material which produces at the test site "color visible to the unaided eye". No substrate addition is necessary to develop color.
- Since the claims contain an opening language, they fails to exclude any additional materials such as a substrate to develop "color to the unaided eye".
- Applicant also submits that Brown III fails to disclose "conjugate comprising the colored particulate material that moves along the flow path".
- Brown III teaches that a second labeled reagent which can be bound to the analyte which is bound by the reagent retained within the matrix and that the label of the second reagent produces detectable response which is indicative of the presence and/or amount of the analyte. Such a detectable response can be read visually and can advantageously be a color response. (see col. 4, lines 4-19). Obviously, the second label reagent moves free along the flow path to bind to the analyte that has been bound to the immobilized particles.

Conclusion

- Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is (703) 308-4398. The examiner can normally be reached on Mon-Fri. from 8 a.m. to 5 p.m.

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- If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.
- Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/641

Pensee T. Do
Patent Examiner
December 21, 2001